



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Certified/Return Receipt Requested

March 27, 1998

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Paul Hough, President
Van Waters & Rogers, Inc.
6100 Carillion Point
Kirkland, WA 98033

Ref. # - KAN-98-013

Dear Mr. Hough:

During an inspection of your bulk drug repacking facility located in Omaha, Nebraska, conducted on March 12 to 13, 1998, our investigator documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause the drug products at this facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Observations include, but are not limited to the following: 1) failure to have in place written procedures covering specifications for acceptance of the bulk drugs, and specific test procedures; 2) failure to periodically validate the reliability of the certificates of analysis from the bulk drug suppliers; 3) failure to show that the identification test method being used is equal to or better than the USP test method; 4) failure to maintain equipment maintenance documentation, or perform equipment calibration routinely.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations, at each facility. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. Additionally, export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

Page 2
March 27, 1998
Van Waters & Rogers Inc.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps that are being taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Sam H. J. Salzman (for)
W. Michael Rogers
District Director
Kansas City District

cc: Barry Kopf, Branch Manager
Van Waters & Rogers, Inc.
3002 F Street
P.O. Box 7900
Omaha, NE 68107